

510(k) SUMMARY

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1. SUBMITTER:

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Contact: Eric Bannon, Director of Quality Assurance and Regulatory Affairs  
Date Prepared: August 29, 1995

2. DEVICE:

Innovasive 1.9mm ROC Suture Bone Fastener  
Classification Name: Single/multiple component bone fixation appliances and accessories.  
Trade Name: Innovasive Devices ROC Suture Bone Fastener

3. PREDICATE DEVICE:

The predicate device used to determine substantial equivalence for the Innovasive Devices 1.9mm Roc Suture Bone Fastener was Ethicon USP #2/0 braided polyester suture with suture button.

4. DEVICE DESCRIPTIONS:

The Innovasive ROC Suture Bone Fastener is an implantable soft tissue fixation device complete with the instrumentation needed to effect soft tissue to bone repair. The devices consist of a high density polyethylene cartridge with an acetal drive pin which is deployed into a pre-drilled hole in the bone. The Fastener is deployed through the use of a deployment handle made of molded polysulfone. The Fastener also has a stainless steel drive tool inside the cartridge which shears the implantable Fastener when deployed by the handle. The Fastener comes with various non-absorbable suture material.

In addition to the Fastener, a stainless steel drill and drill guide is available to establish the proper hole for in the bone for the Fastener. A stainless steel and polysulfone extractor is included which can be used to remove the deployed Fastener should it be necessary. All of the instrumentation except the Fastener will be offered as reusable devices and can be autoclaved in the sterilization tray provided for this purpose.

The Fastener will be available as a sterile, single use device in both an open and arthroscopic version. Both sutured and sutureless versions will be marketed.

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## **5. INTENDED USE:**

The Innovasive Devices 1.9mm ROC Suture Bone Fastener is intended for the reattachment of the ulnar collateral and lateral collateral ligaments in the thumb and the scapholunate ligament in the wrist.

## **6. COMPARISON OF CHARACTERISTICS:**

The Innovasive Devices ROC Suture Bone Fastener is comprised of two polymer components, high density polyethylene and acetyl plastic. This device is used to secure suture in a predrilled hole in bone. It remains fixed in the bone through radial compression as the device is deployed. This remains true for all sizes of the device.

The Ethicon suture is comprised of braided polyester fibers and the suture button is comprised of molded polypropylene. The devices are used in conjunction with each other to reattach soft tissue to bone. The suture is passed through the bone and tissue and fixed with a suture button. This approximates the tissue to the bone to allow the final repair.

## **7. PERFORMANCE DATA:**

The following performance data was provided in support of the substantial equivalence determination:

1. Cadaver study: Comparison of the ultimate holding strength in the bone indicated compared to the predicate device. The Innovasive Suture Bone Fastener holding strength was found to be equivalent to the strength of the predicate device.